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EXAMINER	
DUFFY, BRADLEY	
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1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,618	KEHOE-WHISTANCE ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-33 and 38-47* is/are pending in the application.

4a) Of the above claim(s) *5-9,11,12,15,16,20,28,32,33,38-40,42-44 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,10,13,14,17-19,21-27,29-31,41,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed December 10, 2009, is acknowledged and has been entered. Claims 1, 4, 5, 6 and 32 have been amended. Claim 3 has been canceled. Claims 40-47 are newly added.

2. The election with traverse filed December 10, 2009, is acknowledged and has been entered.

Applicant has elected the invention of Group I, claim 4, drawn to a method of treating breast cancer which comprises administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and a second amount of an immunogen comprising a MUC1 epitope, effective to contribute to the development of a protective immune response to said breast cancer, where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers. Applicant has further elected tamoxifen as the species of anti-estrogenic agent administered. Linking claims 1, 2, 10, 13, 14, 17-19, 21-27, 29-31, 41, 45 and 46 read on the elected invention and elected species of invention. Notably, as set forth in claim 30, tamoxifen is a Selective Estrogen Receptor Modulator (SERM) which agonizes at least one other estrogen receptor, so claims 28 and 47 which recite that the agent does not agonize other estrogen receptors have been withdrawn as they do not read on the elected species of the invention.

3. Claims 1, 2, 4-33 and 38-47 are pending in the application.

4. Claims 5-9, 11, 12, 15, 16, 20, 28, 32, 33, 38-40, 42-44 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention or non-elected species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed December 10, 2009.

5. Claims 1, 2, 4, 10, 13, 14, 17-19, 21-27, 29-31, 41, 45 and 46 are under examination.

Election/Restrictions

6. Applicant's traversal of the restriction and election requirement set forth in the Office action mailed September 10, 2009, is acknowledged.

Applicant's arguments have been carefully considered but have not been found persuasive for the following reasons:

Applicant appears to be traversing the restriction requirement on the grounds that the claims have now been amended to comprise a special technical feature which distinguishes over the prior art. Based on this amendment Applicant requests withdrawal of the restriction requirement and rejoinder of all pending groups.

In response, Applicant's request for rejoinder is currently premature because all the claims drawn to the elected invention are not allowable. Notably, as set forth in MPEP 1893.03(d), "If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder".

Therefore, because the claims drawn to the elected invention are not allowable, for the reasons set forth below, Applicant's request for rejoinder is currently moot and the restriction requirement has not been obviated. Furthermore, it is noted that PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept to comprise more than the first mentioned product, the first mentioned method for making said product, and the first mentioned method for using said product.

Finally, while it is acknowledged that Applicant appears to argue that claims 5 and 6 should be examined because the elected invention which administers a MUC1 epitope does not foreclose the additional administration of the epitopes of claims 5 and 6, it is further noted that claims 5 and 6 do not depend from claim 4 and the elected method of claim 4 does not require administration of the epitopes of claims 5 and 6.

Accordingly, it is maintained that Groups I-III are not linked by a special technical feature.

Therefore, for these reasons and the reasons set forth in the Office action mailed September 10, 2009, the restriction/election requirement is deemed proper and therefore made FINAL.

Information Disclosure Statement

7. The references cited in the information disclosure statement filed on December 10, 2009, have been considered.

Specification

8. The disclosure is objected to for the following reasons:

(a) The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified. Reference to hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified is impermissible and therefore requires deletion.

Examples of such impermissible disclosures appear in the specification at, for example, page 37, lines 26-27.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding acceptable incorporation by reference. See 37 CFR § 1.57.

MPEP 608.01(p) does not provide for incorporation of essential *or* non-essential material by reference to, for example, hyperlinks or other forms of browser-executable code. Essential subject matter may only be incorporated by reference to (1) US patents and pending US applications, or patents or other publications published by a foreign country or a regional patent office, (2) non-patent publications, (3) a US patent or

application which itself incorporates material by reference, or (4) a foreign application. Non-essential information may be incorporated by reference to (1) patents or applications published by the United States, or patents or other publications published by a foreign country or a regional patent office, (2) prior filed, commonly owned US applications, (3) non-patent publications.

Not provided for by MPEP 608.01(p) is the incorporation of any material, whether essential or not, by reference to a website or the contents thereof.

It is impermissible that a patent's disclosure incorporate essential or non-essential material by reference to, for example, embedded hyperlinks and/or other forms of browser-executable code, because the information contained in the websites or databases to which the hyperlinks or other forms of browser-executable code connect may not be maintained on the Internet for the duration of the patent's term and may not contain the same information after the filing date of an application that was contained in the website or database on or before the filing date of the application. Since the information contained in a website may vary, it is not evident that information contained in a website will always remain useful to the practitioner or even applicable to the invention; and information contained in an extinct website cannot possibly be helpful to the practitioner. Furthermore, the validity of a patent containing a reference to a hyperlink or other form of browser-executable code may be reasonably questioned if the website(s) to which the hyperlink(s) connect were relied upon by the patentee(s) to provide sufficient disclosure or description of the invention to meet the requirements of 35 USC § 112, first and second paragraphs. As such, recitation of such references is not permitted.

A hyperlink or other form of browser-executable code may be permitted <u>if the hyperlink or other form of browser-executable code is part of the claimed invention</u>, but in such a case, the Office would disable the hyperlink or other form of browser-executable code.

In general, if the Applicant expects to rely upon the information contained in the websites or databases to provide antecedent basis for the subject matter of claims in a parent application or related applications, and if the material is properly incorporated by

reference in the referencing application, Applicant would be required to amend the specification of the referencing application to include the material incorporated by reference to the hyperlink or other forms of browser-executable web, or other non-permissible sources and to provide a declaration by Applicant or Applicant's representative stating that the amendatory material consists of the same material incorporated by reference in this application. See MPEP § 608.01(p).

If Applicant intends that information contained at the websites to which the disclosures refer be incorporated, Applicant is required to amend the specification to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by Applicant, or a practitioner representing Applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

(b) The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite because claim 10 from which claim 13 and 14 ultimately depend recite a steroid agent, but claim 13 recites that this steroid agent is

non-steroidal. Accordingly, it is unclear and cannot be determined how a steroid agent can also be considered a non-steroidal agent. Accordingly, it is submitted that these claims fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

Therefore, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a “written description” rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description'' Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereinafter “Guidelines”). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, “the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the

applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention*.

In the instant case, claim 21 is broadly drawn to methods of treating breast cancer which comprises administering, to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and a second amount of an immunological agent, effective to contribute to the development of a protective immune response to

said breast cancer, where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers where said immunological agent comprises at least one immunogen, said immunogen comprising at least one breast cancer-associated epitope, in which the combination of the anti-estrogenic steroid agent and the immunological agent is ***synergistically*** effective against breast cancer. Notably, the claims do not set forth any doses of these agents that act synergistically and the specification similarly does not provide any guidance as to what doses of these agents in combination would create synergy in treating breast cancer. Therefore, one of skill in the art would not conclude that applicant was in possession of methods of administering an anti-estrogenic steroid agent and an immunogen comprising at least one breast cancer-associated epitope that are ***synergistically*** effective against breast cancer because one of skill in the art would not be able to immediately envision or recognize which combinations of these agents would provide synergy from those that would not provide synergy.

In this case the term "synergism" is defined in the relevant art, for example, by Stedman's Online Medical Dictionary, 27th Edition as meaning: "Coordinated or correlated action of two or more structures, agents, or physiologic processes so that the combined action is greater than the sum of each acting separately" (Copyright © 2007 Lippincott Williams & Wilkins). Similarly, the specification at page 48 sets forth that the agents "are used at such times as to have a synergistic effect, that is, the combined effects are greater than those which would be reasonably expected as the simple additive effect of the individual therapies". Given these definitions of synergism, one of skill in the art would reasonably conclude that the claims are directed to combinations of the recited agents that provide a combined action greater than the sum of each acting separately to treat breast cancer. In notable contrast, however, the specification does not set forth any combinations of the agents that have been shown to act with synergy and therefore one of skill in the art could not immediately envision which combinations or times of administration would display synergy to treat breast cancer from those that would not. Accordingly, one of skill in the art would not reasonably conclude that Applicant was in possession of the genus of methods wherein the agents are

synergistically effective against breast cancer.

Given the lack of particularity with which the claimed "synergistic methods" are described in the specification, it is submitted that the skilled artisan could not immediately envision, recognize or distinguish at least most of the members this genus, to which the claims are directed; and therefore the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 2 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahlert et al (J. Clin. Onc., 15(4):1354-1366, 1997, IDS filed 12/10/09) as evidenced by Buzdar et al (Clin. Can. Res., 4:527-534, 1998).

The claims are herein drawn to method comprising administering to a subject with breast cancer or metastatic breast cancer a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and a second amount of an immunological agent, effective to contribute to the development of a protective immune response to said breast cancer, where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers, where said immunological agent comprises at least one immunogen, said immunogen comprising at least one breast cancer-associated epitope. Claim 2 recites that the agents are administered concurrently. In this case, the specification does not explicitly define concurrent administration as simultaneous administration, so concurrent administration is being broadly, but reasonably interpreted to include administration of the two agents separately to the same breast cancer patient

in conjunction or in combination with one another. For example, Merriam-Webster's Online Dictionary, 10th Edition (copyright © 2010 by Merriam-Webster, Inc.), which is available on the Internet at <http://www.m-w.com/>, defines the term "concurrent" as:

1: operating or occurring at the same time

2 a : running parallel **b :** CONVERGENT; *specifically* **:** meeting or intersecting in a point

3 : acting in conjunction.

Notably, as evidenced by Buzdar et al anti-estrogenic agents are considered standard hormonal agents for the hormonal treatment of breast cancer (see entire document, e.g., abstract).

Ahlert et al teach methods comprising administering to a subject with breast cancer standard hormonal agents known to treat breast cancer and an immunogen comprising at least one breast cancer-associated epitope, i.e., an autologous breast tumor cell immunogen to induce an immune response and these agents are administered to subjects in conjunction with each other. Ahlert et al also teach methods administering to a subject with metastatic breast cancer a hormonal agent known to treat breast cancer and an immunogen comprising at least one breast cancer-associated epitope, i.e., an autologous breast tumor cell immunogen, to induce an immune response (see entire document, e.g., page 1355 and 1361). Accordingly, because Ahlert et al teach administration of standard hormonal agents that as evidenced by Buzdar et al inherently are anti-estrogenic agents, in referencing standard hormone therapy Ahlert et al inherently teaches administration of anti-estrogenic agents.

Accordingly, Ahlert et al teach methods that are materially and manipulatively indistinguishable from the instantly claimed methods. Therefore, absent a showing of any difference, the methods disclosed by the prior art are deemed to anticipate the claimed invention.

15. Claims 1, 2, 4 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilewski et al (Clin. Can. Res., 6:1693-1701, 2000) as evidenced by Buzdar et al (Clin. Can. Res., 4:527-534, 1998).

The scope of Claims 1, 2 and 31 are set forth supra. Claim 4 further limits the method of claim 1 to an immunogen comprising a MUC1 epitope

Gilewski et al teach methods comprising administering to breast cancer subjects a hormonal agent known to treat breast cancer and a MUC1 immunogen to induce an immune response to the immunogen and that these agents are administered to subjects in conjugation with each other. (see entire document, e.g., page 1694). Accordingly, because Gilewski et al teach administration of hormonal agents that as evidenced by Buzdar et al inherently are anti-estrogenic agents, in referencing hormone therapy Gilewski et al inherently teaches administration of anti-estrogenic agents.

Accordingly, Gilewski et al teach methods that are materially and manipulatively indistinguishable from the instantly claimed methods. Therefore, absent a showing of any difference, the methods disclosed by the prior art are deemed to anticipate the claimed invention.

16. Claims 1, 2, 4, 10, 13, 14, 17-18, 22-27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by McCluskie et al (US 20010044416 A1, 2001).

The scope of Claims 1, 2, 4 and 31 are set forth supra. The additional claims are further drawn to the anti-estrogen agent being the Selective Estrogen Receptor Modulator (SERM) tamoxifen and further administering progesterone, doxorubicin or paclitaxel to the subject.

McCluskie et al teach methods comprising administering to breast cancer subjects a MUC1 immunogen to induce an immune response to the immunogen, and hormone therapy including tamoxifen alone or in combination with progesterone. McCluskie et al teach that the methods can further comprise administering chemotherapeutic agents such as paclitaxel or doxorubicin (see entire document e.g., pages 23 and 24, claims 1 and 6).

Accordingly, McCluskie et al teach methods that are materially and manipulatively indistinguishable from the instantly claimed methods. Therefore, absent a showing of any difference, the methods disclosed by the prior art are deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1, 2, 10, 13, 14, 17-19, 27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlert et al (J. Clin. Onc., 15(4):1354-1366, 1997, IDS filed 12/10/09) in view of Buzdar et al (Clin. Can. Res., 4:527-534, 1998).

The scope of Claims 1, 2 and 31 are set forth supra in the above rejection of the claims under 102(b). The additional claims are further drawn to the anti-estrogen agent being the Selective Estrogen Receptor Modulator (SERM) tamoxifen and further administering progesterone or an anti-progestin to the subject.

Ahlert et al teach what is set forth in the above rejection of the claims under 102(b). While Ahlert et al teaches administering an autologous tumor cell immunogen and hormonal therapy, along with adjuvant chemotherapy and radiation, Ahlert et al does not expressly teach administering the hormonal therapies tamoxifen, progesterone or an anti-progestin to breast cancer subjects. This deficiency is made up for in the teachings of Buzdar et al.

Buzdar et al teach that teach that administering tamoxifen, progesterone or an anti-progestin to breast cancer subjects was known in the art. (see entire document, e.g., pages 527 and 532).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer tamoxifen and progesterone and/or an anti-progestin along with the autologous tumor cell immunogen of Ahlert et al.

Notably, based on the teachings of Buzdar et al one of skill in the art would immediately recognize that tamoxifen, progesterone or an anti-progestin are hormonal agents species effective in breast cancer patients so one of skill in the art would have been motivated to administer one or more of these agents to breast cancer patients along with the autologous tumor cell immunogen of Ahlert et al to effectively treat the subject's breast cancer. One of skill in the art would have been further motivated to also administer one or more of these agents because Ahlert et al evidence that hormonal agents were being administered to patients that also received administration of autologous tumor cell immunogen. Accordingly, one of skill in the art would not have considered it inventive to predictably substitute and/or add administration of

tamoxifen and progesterone and/or an anti-progestin to treat a subject's breast cancer since administration of these agents to breast cancer patients was taught by the art. Furthermore, because administration of these agents to breast cancer patients was taught by the art, one of skill in the art clearly would have had a reasonable expectation of success in administering such agents to breast cancer patients, in view of these references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

20. Claims 1 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlert et al (J. Clin. Onc., 15(4):1354-1366, 1997, IDS filed 12/10/09) in view of Nabholtz et al (Onc., 6(S3)5-12, 2001).

The scope of Claim 1 is set forth supra in the above rejection of the claims under 102(b). The additional claims are further drawn to administering doxorubicin or paclitaxel to the subject.

Ahlert et al teach what is set forth in the above rejection of the claims under 102(b). While Ahlert et al teaches administering an autologous tumor cell immunogen and hormonal therapy, along with adjuvant chemotherapy and radiation, Ahlert et al does not expressly teach administering doxorubicin or paclitaxel as chemotherapy to breast cancer subjects. This deficiency is made up for in the teachings of Nabholtz et al.

Nabholtz et al teach that teach that administering doxorubicin or paclitaxel as chemotherapy to breast cancer subjects was known in the art (see entire document, e.g., abstract).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer doxorubicin and/or paclitaxel as chemotherapy along with the autologous tumor cell immunogen and hormone therapy of Ahlert et al.

Notably, based on the teachings of Nabholtz et al one of skill in the art would immediately recognize that doxorubicin and/or paclitaxel are chemotherapeutic agent species effective in breast cancer patients so one of skill in the art would have been

motivated to administer one or more of these agents to breast cancer patients along with methods of Ahlert et al to effectively treat the subject's breast cancer. One of skill in the art would have been further motivated to also administer one or more of these agents because Ahlert et al evidence that adjuvant chemotherapy was being administered to patients that also received treatment taught by Ahlert et al. Accordingly, one of skill in the art would not have considered it inventive to predictably add administration of doxorubicin and/or paclitaxel to treat a subject's breast cancer since administration of these agents to breast cancer patients was taught by the art. Furthermore, because administration of these agents to breast cancer patients was taught by the art, one of skill in the art clearly would have had a reasonable expectation of success in administering such agents to breast cancer patients, in view of these references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

21. Claims 1, 2, 4, 10, 13, 14, 17-19, 27, 29-31, 41, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilewski et al (Clin. Can. Res., 6:1693-1701, 2000) in view of Buzdar et al (Clin. Can. Res., 4:527-534, 1998).

The scope of Claims 1, 2, 4 and 31 are set forth supra in the above rejection of the claims under 102(b). The additional claims are further drawn to the anti-estrogen agent being the Selective Estrogen Receptor Modulator (SERM) tamoxifen and further administering progesterone or an anti-progestin to the subject.

Gilewski et al teach what is set forth in the above rejection of the claims under 102(b). While Gilewski et al teaches administering a MUC1 immunogen and hormonal therapy, Gilewski et al does not expressly teach administering the hormonal therapies tamoxifen, progesterone or an anti-progestin to breast cancer subjects. This deficiency is made up for in the teachings of Buzdar et al.

Buzdar et al teach that teach that administering tamoxifen, progesterone or an anti-progestin to breast cancer subjects was known in the art. (see entire document, e.g., pages 527 and 532).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer tamoxifen and progesterone and/or an anti-progestin along with the MUC1 immunogen of Gilewski et al.

Notably, based on the teachings of Buzdar et al one of skill in the art would immediately recognize that tamoxifen, progesterone or an anti-progestin are hormonal agents species effective in breast cancer patients so one of skill in the art would have been motivated to administer one or more of these agents to breast cancer patients along with the MUC1 immunogen of Gilewski et al to effectively treat the subject's breast cancer. One of skill in the art would have been further motivated to also administer one or more of these agents because Gilewski et al evidence that hormonal agents were being administered to patients that also received administration of autologous tumor cell immunogen. Accordingly, one of skill in the art would not have considered it inventive to predictably substitute and/or add administration of tamoxifen and progesterone and/or an anti-progestin to treat a subject's breast cancer since administration of these agents to breast cancer patients was taught by the art. Furthermore, because administration of these agents to breast cancer patients was taught by the art, one of skill in the art clearly would have had a reasonable expectation of success in administering such agents to breast cancer patients, in view of these references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

22. Claims 1 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilewski et al (Clin. Can. Res., 6:1693-1701, 2000) in view of Nabholtz et al (Onc., 6(S3)5-12, 2001).

The scope of Claim 1 is set forth supra in the above rejection of the claims under 102(b). The additional claims are further drawn to administering doxorubicin or paclitaxel to the subject.

Gilewski et al teach what is set forth in the above rejection of the claims under 102(b). While Gilewski et al teaches administering an MUC1 immunogen and hormonal therapy, Gilewski et al does not expressly teach administering doxorubicin or paclitaxel to breast cancer subjects. This deficiency is made up for in the teachings of Nabholtz et al.

Nabholtz et al teach that teach that administering doxorubicin or paclitaxel as chemotherapy to breast cancer subjects was known in the art. (see entire document, e.g., abstract).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer doxorubicin and/or paclitaxel as chemotherapy along with the MUC1 immunogen and hormone therapy of Gilewski et al.

Notably, based on the teachings of Nabholtz et al one of skill in the art would immediately recognize that doxorubicin and/or paclitaxel are chemotherapeutic agents effective in breast cancer patients so one of skill in the art would have been motivated to administer one or more of these agents to breast cancer patients along with methods of Gilewski et al to effectively treat the subject's breast cancer. Accordingly, one of skill in the art would not have considered it inventive to predictably add administration of doxorubicin and/or paclitaxel to treat a subject's breast cancer since administration of these agents to breast cancer patients was taught by the art. Furthermore, because administration of these agents to breast cancer patients was taught by the art, one of skill in the art clearly would have had a reasonable expectation of success in administering such agents to breast cancer patients, in view of these references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

23. Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCluskie et al (US 20010044416 A1 2006) in view of Buzdar et al (Clin. Can. Res., 4:527-534, 1998).

The scope of Claim 1 is set forth supra in the above rejection of the claims under 102(b). Claim 19 further recites administering an anti- progestin to the subject.

McCluskie et al teach what is set forth in the above rejection of the claims under 102(b). While McCluskie et al teaches administering a MUC1 immunogen and the hormone therapy tamoxifen, McCluskie et al does not expressly teach administering an anti-progestin to breast cancer subjects. This deficiency is made up for in the teachings of Buzdar et al.

Buzdar et al teach that teach that administering an anti-progestin to breast cancer subjects was known in the art. (see entire document, e.g., pages 527 and 532).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a MUC1 immunogen and tamoxifen and an anti-progestin.

Notably, based on the teachings of Buzdar et al one of skill in the art would immediately recognize that an anti-progestin is a hormonal agent species effective in breast cancer patients so one of skill in the art would have been motivated to also administer an anti-progestin to breast cancer patients to effectively treat the subject's breast cancer. Accordingly, one of skill in the art would not have considered it inventive to predictably add administration of an anti-progestin to treat a subject's breast cancer since administration of this agent to breast cancer patients was taught by the art. Furthermore, because administration of these agents to breast cancer patients was taught by the art, one of skill in the art clearly would have had a reasonable expectation of success in administering such agents to breast cancer patients, in view of these references.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

24. No claims are allowed.

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Koentgen (US 20040029179 A1, 2004) teaches methods of administering a MUC1 immunogen and tamoxifen to breast cancer subjects. Reddish et al (Int. J. Can., 76:817-813, 1998) teaches methods of administering a MUC1 immunogen to breast cancer subjects.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
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